To: Gasdia, Russell[, Mallin, William]

: Mahony, Edward[.

From: Stiles, Gary

**Sent:** Fri 11/1/2013 9:24:59 AM

Subject: RE: Board Notes & Actions - Please Return Your Coments and Edits

Only correction on my to do list is that we will provide topline data on HYD after the appropriate review and QA process as I said at the meeting.

Gary

From: Gasdia, Russell

Sent: Friday, November 01, 2013 9:06 AM

To: Stewart, John H. (US); Mallin, William; Mahony, Edward

Cc: Richards, Tim; Stiles, Gary; Dolan, James

Subject: RE: Board Notes & Actions - Please Return Your Coments and Edits

Looks like it captured what I recall

From: Stewart, John H. (US)

**Sent:** Friday, November 01, 2013 7:35 AM **To:** Mallin, William; Mahony, Edward

Cc: Gasdia, Russell; Richards, Tim; Stiles, Gary; Dolan, James

**Subject:** Board Notes & Actions - Please Return Your Coments and Edits

Importance: High

Bill

This is fairly comprehensive, and captures the follow-up actions/issues that I noted – so with a bit of re-organization and expansion of the actions being requested, this can easily become the notes and actions from the meetings.

I have copied Russ, Tim, Gary, and Jim to see if they have any points to add and/or expand upon.

Thanks - js

From: Mallin, William

**Sent:** Thursday, October 31, 2013 8:59 AM **To:** Stewart, John H. (US); Mahony, Edward

Cc: Mallin, William

Subject: FW: Board Notes & Actions - Day One and Day Two Raw Notes

Second day notes:

#### Gents:

Raw notes from day two. Please consider adding yours and we should then review/reduce to only those that require response or meaningful action.

Bill

## Gary Stiles/et al

- 1. Provide specific metrics for how much abuse is seen in other opioids, including IR, APAP, and NSAIDs, compared to ER opioids and Oxy specifically. Complete morbidity and mortality data. (Paolo).
- 2. While we have much solid data, it does not seem to matter to patients, prescribers, and managed care. What is the compelling economic argument that shows we can reverse our revenue slide? (Dr R/Ralph)
- 3. Board wants to see the topline data from HYD as soon as it is available (Dr K)
- 4. How can we take advantage of electronic health records for tracking abuse? (Ralph)
- 5. With HYD tables all being the same size, concern over lack of color differentiation (Mortimer)
- 6. Should we develop an AR IR hydrocodone? (Jon)
- 7. Should we re-examine the OIC strategy for Targiniq and consider broadening the claim? (Jon)
- 8. Ensure with headcount that pharma-covigilence is not short-changed (Cecil)

#### Jim Dolan

- 1. General question as to why we were pursuing the opportunity, why the big companies in the space were not pursuing this, what evidence exists to know that oral is preferred (ref: EU) likely the Board would not act quickly enough with a non-binding offer in the timeframe required, punted to the Board Corp Dev Committee (All)
- 2. The opportunity was brought up and requested to be reconsidered ((Mortimer)
- 3. PG transdermal pouch for (**did not get the product name**) should be explored (Ralph)

Raul Damas

- 1. Modify the mission to keep away from "achieve Purdue's commercial objectives" to be broader with respect to serving patients/physicians, etc (Mortimer, Dr K)
- 2. CDC data- why has it not been updated since 2010 and therefore, more reflective of the potential impact ORF has had? (Paolo)
- 3. How can we identify patients at risk for abuse on a state by state basis? Could we pilot a patient access program in one state? (Ralph)

## Legal

Nothing other than the multiple and complex issues surrounding the proposal for possible negotiation with Business Development Committee (J. Lewent, Dr K, Jon, Mortimer, David S, Paolo) by Friday Nov 1.

From: Mallin, William

**Sent:** Wednesday, October 30, 2013 8:19 AM **To:** Stewart, John H. (US); Mahony, Edward

Cc: Mallin, William

**Subject:** Board Notes & Actions - Day One Raw Notes

### Gents:

Raw notes from the meeting day one. We can review for the meaningful actions once today is completed.

#### JHS

- 1. Do we have a full understanding of the FDA and their policy regarding development of opioids? Is our current AR strategy sound? (Dr K.Dr R)
- 2. Consider making direct contact with the FDA
- 3. Do we have any freedom of information access to data concerning overdose and abuse with IR opioid products? (Paolo)
- 4. Has there been any sign of congressional interest/concern with decision? Who will market the product? Can we confirm their AR development plans? Fast track a deal that is good for (Purdue (Jon Mortimer)
- 5. Targiniq-What will be in the label and what can we say about this product? (this also comes up later during managed care (Cecil)
- 1. For OxyContin are we doing research or tracking patients with regards to the erosion of higher doses? Is this affecting the patient population or is this related to physicians emerging reluctance to prescribe higher doses. Are patients being actively switched off higher doses? (Ralph)

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#### Russ

- 2. Butrans Concern over the lack of growth rate in scripts. Can we explore specific populations (elderly) and/or can we re-allocate resources (Mortimer)
- 3. Are we clear on our messages and specific about what patients (for Butrans and Targiniq going forward) we are marketing to given our indication(s)? (Judy)
- 4. If Butrans is expected to peak at \$350mm, what percentage of that will be Med D coverage? What evidence based studies will we have to achieve the level of managed care coverage we need? (Dr K)

#### David Rosen

- 1. What will be the impact of up-scheduling the combination products like Vicodin have on the ERO market? What market research is planned (aside from following NYS) that may provide data on the impact to OxyContin, Butrans and the new products? (Jon)
- 2. What is the impact of the Affordable Healthcare Act on our products, current and planned? (Ralph)
- 3. What are the pricing assumptions for any of our AR products over a generic equivalent? What would managed care pay for this (30% premium is assumed) (Jon)
- 4. Find a way to find the "voice" of prescribing physicians in a way to help our products.(Ralph)

# Mike Ronning

- Must focus on sales force incentives (behaviors) not just push to obtain scripts – integrate this across the entire culture not just sales – language, attitude, etc – do well by doing good (Dr K/Judy)
- 2. Beware of upsetting existing rep/practitioner relationships and expect 20% disruption costs (Paolo)
- 3. How to take care of medical grand rounds, ACO's, patient advocacy and other indirect avenues for influencing treatment of pain (Ralph)

## Tim Richards/Todd Killian

- 1. A general discussion of pricing for Targiniq v OxyContin and a question concerning whether or not to have both products on the market and what reaction practitioners may have to the naloxone component for existing patieints (Mortimer- Cecil)
- 2. What will be in th Targiniq label, what studies can be presented to

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managed care, can we use EU study data and peer review journals (Mortimer) . I think this is an issue to be presented at a separate Board meeting.

Bill

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